PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of	Docket No: Q88613
Pascal DENOLLY	
Appln. No.: 10/539,577	Group Art Unit: 3763
Confirmation No.: 4484	Examiner: Quynh-Nhu Hoang VU
Filed: June 17, 2005	

For: DISTRIBUTION DEVICE FOR A SUPPLY NETWORK FOR SUPPLY OF MEDICAL FLUIDS TO A PATIENT

SUBMISSION OF APPEAL BRIEF

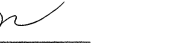
MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith please find an Appeal Brief. An Appeal Brief was *previously* filed on December 23, 2008. The Examiner thereafter reopened prosecution. The present submission reinstates the Appeal. **Accordingly, Applicant submits that the statutory fee of $270.00 should not be charged.**

The USPTO is directed and authorized to charge required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 37 C.F.R. § 41.37, Appellant submits the following:

Table of Contents

I. REAL PARTY IN INTEREST

The real party in interest in this Appeal is SEDAT of France. The assignment was previously submitted and was recorded on December 14, 2005 at Reel 017715, Frame 0092.

II. RELATED APPEALS AND INTERFERENCES

To the knowledge and belief of Appellant, the Assignee and the Appellant's legal representative, there are no other appeals or interferences before the Board of Appeals and Interferences that will directly affect or be affected by the Board's decision in the instant Appeal.

III. STATUS OF CLAIMS

Claims 2-12 are pending and are the basis of this Appeal.

Claims 2-12 stand rejected. See Claims Appendix for listing of rejected claims.

Claim 1 was previously canceled in the November 20, 2007 Amendment.

IV. STATUS OF AMENDMENTS

Appellant did not amend the claims subsequent to the April 28, 2009 Office Action. Accordingly, all amendments, which have been made during prosecution of the present application, have been entered.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The present invention is directed to a distribution device for a system for delivery of medical fluids to a patient. The features of independent claim 1 are described herein in reference to non-limiting embodiments of Appellant's specification.

Claim 12 - Claim 12 recites a distribution device for a system (1) for delivery of medical fluids to a patient. The device includes a syringe body (30) **(Fig. 1)** and a feed tube (56) for an active medical fluid, opening into the syringe body (30) and designed to be connected to a reservoir (6) for the active medical fluid **(Figs. 1 and 2; pg. 7. lines 8-12; pg. 8, lines 20-29)**.

A distributor (32) includes a distributor body (32B), within which there is bounded a chamber (62) for fluid circulation, and within the chamber (62) there are both a slide (112), which can move in relation to the distributor body (32B) and which forms, with walls of the chamber, a compartment (126), and a resilient member (120) placed between the slide (112) and a fixed part (122) of the distributor body **(Figs. 1 and 2; pg. 8, line 30 to pg. 9, line 4; pg. 11, line 28 to pg. 12, line 2)**. An injection tube (60) is provided for the injection of the active medical fluid, connected to a distal extremity (46) of the syringe body (30) and opening into the chamber (62) **(Figs. 1 and 2; pg. 8, line 32 to pg. 9, line 2)**.

A pressurised tube (64) is provided and is designed to be connected to the patient through a pressurised line (12) of the system (1), and opening into the chamber (62) **(Figs. 1 and 2; pg. 9, lines 5-13)**. A pressure measurement tube (66) is provided and is designed to be connected to

a pressure measurement line (16) of the system (1), and opening into the chamber (62) **(Figs. 1 and 2; pg. 7, lines 20-22; pg. 9, lines 5-13)**.

A flush tube (68) is provided. The flush tube is separate from other tubes (56, 60, 64, 66) of the device, is formed in the distributor body (32B) and includes a first section (68A), which is designed to be connected to a reservoir (24) for a flush medical fluid, and a second section (68B) opening directly into the chamber (62). The flush tube (68) is fitted with a valve (70, 80) equipped with a plug (70) which is located between the first and second sections (68A, 68B) of the flush tube **(Figs. 1 and 2; pg. 9, lines 5-28)**. The valve can be moved manually between a position in which it at least partly closes the flush tube and a position in which the flush tube (68) is in free communication with the chamber (62) **(Figs. 1 and 2; pg. 9, line 14 to pg. 10, line 3)**.

The distributor (32) provides an automatic connection via the chamber (62) between the pressurised tube (64) and either the injection tube (60) or the pressure measurement tube (66) through the action of the pressure of the active medical fluid and the resilient member (120), the active medical fluid circulating via the compartment (126) between the pressurised tube (64) and the pressure measurement tube (66) when they are in connection **(Figs. 1 and 2; pg. 9, lines 5-13; pg. 11, line 28 to pg. 12, line 2)**.

Finally, the distributor (32) connects the flush tube (68) with the pressurised tube (64) and with the pressure measurement tube (66) via the chamber (62), the flush medical fluid circulating via the compartment (126) between the flush tube (68) and the pressure measurement tube (66) when they are in connection **(Figs. 1 and 2; pg. 9, lines 14-32)**.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 8-10 and 12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by over of U.S. Publication No. 2002/0151854 to Duchon et al. ("Duchon")

B. Claims 2-7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Duchon in view of U.S. Patent No. 4,645,496 to Oscarsson et al. ("Oscarsson").

C. Claims 2-7 and 11 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Duchon in view of U.S. Publication No. 2004/0082904 to Houde et al. ("Houde")

VII. ARGUMENT

A. Rejection of claims 8-10 and 12 under 35 U.S.C. § 102(b) in view of Duchon

Claim 12 recites features which essentially are directed a slide (112) of the distributor (32) that forms a compartment (126) within the chamber. When the distributor (32) controls the connection between the pressurised tube (64) and the pressure measurement tube (66), the active medical fluid circulates between the two aforesaid tubes via this compartment (126). Furthermore, when the distributor (32) controls the connection between the flush tube (68) and the pressure measurement tube (66), the flush medical fluid circulates between the two aforesaid tubes via the same compartment (126) (see page 11, line 30 to page 12, line 2, in page 12, lines 15 to 20, and in page 13, lines 20 to 26 of Appellant's specification).

Duchon discloses a distribution device for a system 10 for delivery of medical fluids to a patient. If the recitations of claim 12 are used in order to describe the **Duchon** device as shown in Figures 1 and 7A to 7D of **Duchon**, the **Duchon** device comprises:

a syringe body 18,

a feed tube 78 for an active medical fluid (a radiographic contrast material), opening into the syringe body 18 and designed to be connected to a reservoir 22 for this active medical fluid,

a distributor 26 comprising a body, within which a chamber is bounded, and within this chamber both a slide 362, which can move in relation to the body of distributor 26, and a resilient member 372 placed between slide 362 and a fixed part 374 of distributor 26,

an injection tube 80 for the injection of the active medical fluid, connected to a distal extremity of syringe body 18 and opening into the chamber of distributor 26,

a pressurised tube 84 designed to be connected to the patient through a pressurised line 28 of system 10 and opening into the chamber of distributor 26,

a pressure measurement tube 82 designed to be connected to a pressure measurement line 90+92 of system 10 and opening into the chamber of the distributor 26, and

a flush tube 42 designed to be connected to a reservoir 50 for a flush medical fluid (a saline solution).

The distributor 26 of **Duchon** is designed to provide an automatic connection via its chamber between pressurised tube 84 and either injection tube 80 (see Figure 7D) or pressure measurement tube 82 (see Figures 7A, 7B and 7C) through the action of the pressure of the active medical fluid and resilient member 372. When pressurised tube 84 and pressure measurement tube 82 are thus in connection, the active medical fluid circulates between them via a diagonal passage 376. This diagonal passage 376 is exclusively delimited by the body of slide 362. Consequently, this diagonal passage 376 does **not** constitute a compartment formed by the slide and walls of the chamber of the distributor, as recited in claim 12. In particular, Appellant notes that in Figure 7D of **Duchon**, this "diagonal passage 376" is delimited both by the slide 362 and by walls of the chamber in the distributor 26. However, in Figure 7D, the diagonal passage 376 is **not** fluid circulating. In other words, this diagonal passage 376 enables fluid to circulate only in Figures 7A, 7B and 7C, but in these configurations, the diagonal passage is delimited **only** by slide 362.

Consequently, Appellant submits that the diagonal passage 376 **cannot** constitute a "compartment" as defined in claim 12, because, as recited in the two "wherein" clauses at the end

of claim 12, the "compartment (126)" according to the claimed invention is used for **"fluid circulating"**. In other words, the two fluid circulations specified in the end of claim 12 are in a passage which is formed both into the slide (112) and with walls of the internal chamber (62) of the distributor (32). This passage (called *"compartment"* in claim 12) does not correspond to the "diagonal passage 376" disclosed in **Duchon**, because **Duchon's** "diagonal passage" can connect the tube/port 84 with the tube/port 82 only in a strictly fit way.

Also, claim 12 specifically recites,

> - a pressure measurement tube (66), designed to be connected to a pressure measurement line (16) of the system (1), and opening into the chamber (62), and
> - a flush tube (68) which is separate from other tubes (56, 60, 64, 66) of the device, which is formed in the distributor body (32B) and which comprises a first section (68A), which is designed to be connected to a reservoir (24) for a flush medical fluid, and a second section (68B) opening directly into the chamber (62)...wherein the distributor (32) connects the flush tube (68) with the pressurised tube (64) **and** with the pressure measurement tube (66) via the chamber (62), the flush medical fluid circulating via the compartment (126) between the flush tube (68) and the pressure measurement tube (66) when they are in connection. (emphasis added)

As set forth above, the claimed flush tube is separate from the other tubes and opens "directly" into the chamber. The Examiner maintains that tube 82 of **Duchon** discloses the claimed second section of the flush tube (i.e., a type of flush port of the flush tube 42), where the tube 82 opens directly into the alleged chamber 26 (pg. 3 of April 28, 2009 Office Action). Appellant notes, however, that the Examiner maintains that tube 82 of **Duchon** also discloses the claimed pressure measurement tube (pg. 3 of April 28, 2009 Office Action).

Appellant submits that the tube 82 cannot disclose both the claimed flush tube and the pressure measurement tube. In particular, as noted above, claim 12 recites that both the pressure measurement tube and the flush tube (which includes two sections) open into the chamber and the flush tube is *separate from* the other tubes. Claim 12 also recites that the flush tube is connected with the pressure measurement tube via the chamber. Since the tube 82 is alleged to disclose both a section of the flush tube and the pressure measurement tube, i.e., a single tube, the alleged flush tube and pressure measurement tube of **Duchon** are clearly not connected together via the chamber, let alone via the chamber based on movement of the distributor. Rather, the flush tube 42 of **Duchon** opens in pressure measurement line 90+92. Consequently, in order to flush line 90+92, the flush medical fluid coming from flush tube 42 circulates directly in line 90+92, without circulating in a part of the chamber of distributor 26. In summary, tube 82 of **Duchon** is used **both** for measuring the pressure in distributor 26 and **also** for flushing the distributor, and therefore fails to teach or suggest the claimed features in the specific configuration as claimed.

In regard to the above, Appellant notes that the pressure measuring and the flushing by the device according to the claimed invention are improved because, in the two configurations specified in the two "wherein" clauses at the end of claim 12, the flush fluid circulates in the "compartment (126)", which facilitates and homogenizes the fluid circulation between the different separate "tubes" that are in connection via this compartment as a function of the position of the slide (112).

Furthermore, Appellant submits that **Duchon** is not provided with "a valve equipped with a plug which can be moved manually." As a consequence, the device defined by claim 12 can be distinguished from the **Duchon** device by the following:

First, in the claimed invention, two separate tubes for respectively flushing and pressure measuring open into the chamber of the distributor; in use, the flush medical fluid can circulate between these two separate tubes via a compartment delimited by the walls of the chamber and by the slide; and ***second***, the circulation of the flush medical fluid is controlled by a valve provided in the flush tube, "with a plug which can be moved manually".

The Examiner refers to paragraph [0086] and Figures 2A-G of **Duchon** and maintains that **Duchon** provides either a valve 46 or a valve pinching. Appellant submits, however, that there is not teaching or suggestion of the manual movement. Thus, Appellant submits that claim 12 is patentable over **Duchon** for at least this additional reason.

Due to the invention as claimed, the fabrication of the distributor body is facilitated because the flush tube (68) and the pressure measurement tube (66) extend independently from each other up to the chamber (62) of the distributor body (32B). Also, the distributor body can be designed in a very compact way in the sense that the second section (68B) of the flush tube (68) can be very short. Thus, the fabrication of the distributor body according to the claimed invention is facilitated because the flush tube (68) and the pressure measurement tube (66) extend independently from each other up to the chamber (62) of the distributor body (32B).

Additionally, the pressure measuring and the flushing by the device according to the claimed invention are improved because the compartment (126) facilitates and homogenizes the

circulation of the two medical fluids between the different separate tubes that are in connection via this compartment, in function of the position of the slide (112). In particular, the formation and the trapping of bubbles is considerably reduced (especially in comparison with diagonal passage 376 in slide 362 of the **Duchon** device, this diagonal passage being provided to connect tube 84 with tube 82 in a strictly fit way).

At least based on the foregoing, Appellant submits that claim 12 is patentable over Duchon.

Also, Appellant submits that claims 8-10 are patentable at least by virtue of their dependency upon claim 12.

B. Rejection of claims 2-7 under 35 U.S.C. § 103(a) in view of Duchon and Oscarsson

Since claims 2-7 are dependent upon claim 12, and Oscarsson fails to cure the deficient teachings of Duchon, at least in regard to claim 12, Appellant submits that claims 2-7 are patentable at least by virtue of their dependency.

In addition, the Examiner acknowledges that **Duchon** is silent as to whether the valve disclosed therein includes the structure recited in the claims. Accordingly, the Examiner cites to **Oscarsson**.

Appellant respectfully traverses the Examiner's Assertion. One skilled in the art would not be motivated to modify **Duchon** in view of **Oscarsson** to arrive at the claimed invention. For example, **Oscarsson** discloses a distribution device A comprising a valve with a plug located

between a first tube section 14 and a second tube section 22. The **Oscarsson** device further comprises a pressure measurement tube 34 which opens into the middle part of tube section 22, between plug 80 and a female fitting 28. The aforesaid middle part of tube section 22 is totally free, that is to say, it is not provided with a movable slide through which a flush fluid coming from plug 80 could be circulated (see Figure 5). In other words, the flush fluid coming from plug 80 circulates **directly** between the middle part of tube section 22 and, for one part of the fluid, tube 34 and, for the rest of the fluid, the inside of fitting 28.

If **Duchon** and **Oscarsson** were combined, a man ordinarily skilled in the art is necessarily taught to replace line 90 of the **Duchon** device by the **Oscarsson** device in view of improving the flushing and the pressure measuring. In other words, the man ordinarily skilled in the art would connect female fitting 28 of the **Oscarsson** device to tube 82 of the **Duchon** device, while connecting the pressure transducer 38 of the **Duchon** device to the free end of tube 34 of the **Oscarsson** device, and connecting reservoir 50 of the **Duchon** system to the free end 18 of tube section 14 of the **Oscarsson** device. Thus, the man ordinarily skilled in the art would obtain a distribution device which does **not** correspond to the claimed device, because:

First, the flush tube constituted by tube sections 14 and 22 of the **Oscarsson** device is not formed in the body of distributor 26 of the **Duchon** device because of the presence of fitting 28 between them; ***second***, the assembly of the **Duchon** device and the **Oscarsson** device does not provide two separate tubes opening in the chamber of distributor 26, respectively for the flushing and the pressure measuring (because tube 34 opens directly into tube section 22 of the **Oscarsson** device); and ***third***, the flush medical fluid does not circulate between flush tube

14+22 and pressure measurement tube 34 through the body of distributor 26, especially via a compartment delimited by slide 362 and by the walls of the chamber of distributor 26.

At least based on the foregoing, Appellant submits that claims 2-7 are patentable over the cited references.

C. Rejection of claims 2-7 and 11 under 35 U.S.C. § 103(a) in view of Duchon and Houde

Since claims 2-7 and 11 are dependent upon claim 12 and Houde fails to cure the deficient teachings of Duchon, at least in regard to claim 12, Appellant submits that claims 2-7 and 11 are patentable at least by virtue of their dependency. In addition, even if **Duchon** were modified, as proposed by the Examiner, with **Houde's** feed line, the subject matter of claim 11 would not be produced.

Regarding claims 2-7, the Examiner refers to **Duchon** and maintains that the claimed features would be a mere "rearrangement of parts" (pg. 6 of April 28, 2009 Office Action). As set forth in MPEP § 2144.04, however, the mere fact that the parts of a reference *can* be rearranged is not by itself sufficient to support a finding of obviousness, rather "[t]he prior art must provide a motivation or reason for the worker in the art, without benefit of appellant's specification, to make the necessary changes in the reference device." (emphasis added) *Ex parte Chicago Rawhide Mfg. Co.*, 223 U.S.P.Q. 351, 353 (Bd. Pat. App. & Inter. 1984). **Duchon** fails to provide any teaching or suggestion for the proposed modification. Thus, at this time, the

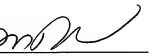
rejection improperly substitutes supposed per se rules for the particularized inquiry required by section 103.

At least based on the foregoing, Appellant submits that claims 2-7 and 11 are patentable over the cited references.

An Appeal Brief was *previously* filed on December 23, 2008. The Examiner thereafter reopened prosecution. The present submission reinstates the Appeal. **Accordingly, Applicant submits that the statutory fee of $270.00 should not be charged**.

The USPTO is directed and authorized to charge required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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CLAIMS APPENDIX

CLAIMS **2-12** ON APPEAL:

2. (rejected): A device according to claim 12, wherein the valve (70, 80) of the flush tube (68) is supported by the body (32B) of the distributor (32).

3. (rejected): A device according to claim 12, wherein the valve (70, 80) is mounted so as to rotate about an axis (Z-Z) orientated transversely to the flush tube (68).

4. (rejected): A device according claim 12, wherein the valve in the flush tube (68) comprises a plug (70) for that tube and a manual control lever (80), the plug and the handle being both connected mechanically to each other and capable of movement with respect to the body (32B) of the distributor (32).

5. (rejected): A device according to claim 4, wherein the plug (70) comprises a sector of a cylinder (74).

6. (rejected): A device according to claim 12, further comprising means (94, 96) for resiliently returning the valve (70, 80) into its closed position.

7. (rejected): A device according to claim 6, wherein the returning means comprises a flexible blade (94) bearing against the body (32B) of the distributor (32) and mechanically connected to the valve (70, 80) of the flush tube (68).

8. (rejected): A device according to claim 12, wherein the body (32B) of the distributor (32) is made of one piece with the body of the syringe (30) in a leaktight manner.

9. (rejected): A device according to claim 12. wherein the tube (56) feeding the first active medical fluid is bounded by the distributor (32).

10. (rejected): A device according to claim 12, wherein the feed tube (56) and the injection tube (60) for the active medical fluid extend in substantially parallel directions.

11. (rejected) A kit for the injection of a contrast product into the human body, comprising:

- a distribution device (2) according to claim 12,

- a feed line (4) for contrast product comprising a flexible conduit (8) fitted with a drip chamber (10) and designed to be connected at one extremity to a reservoir (6) for contrast fluid and at its other extremity to the feed tube (56) of the distribution device (2),

- a pressurised line (12) comprising at one extremity a coronarography catheter (15) designed to be inserted into the patient's body and designed to be connected at its other extremity the pressurised tube (64) of the distribution device (2),

- a pressure measurement line (16) incorporating a conduit (20) fitted with a pressure sensor (18) and designed to be connected to the pressure measurement tube (66) of the distribution device (2), and

- a flush line (22) comprising a flexible conduit (26) fitted with a drip chamber (28) and designed to be connected at one extremity to a reservoir (24) for a flush solution and at its other extremity to the flush tube (68) of the distribution device (2).

12. (rejected): A distribution device for a system (1) for delivery of medical fluids to a patient, comprising;

- a syringe body (30),

- a feed tube (56) for an active medical fluid, opening into the syringe body (30) and designed to be connected to a reservoir (6) for the active medical fluid,

- a distributor (32) comprising a distributor body (32B), within which there is bounded a chamber (62) for fluid circulation, and within the chamber (62) there are both a slide (112), which can move in relation to the distributor body (32B) and which forms, with walls of the chamber, a compartment (126), and a resilient member (120) placed between the slide (112) and a fixed part (122) of the distributor body,

- an injection tube (60), for the injection of the active medical fluid, connected to a distal extremity (46) of the syringe body (30) and opening into the chamber (62),

- a pressurised tube (64), designed to be connected to the patient through a pressurised line (12) of the system (1), and opening into the chamber (62),

- a pressure measurement tube (66), designed to be connected to a pressure measurement line (16) of the system (1), and opening into the chamber (62), and

- a flush tube (68) which is separate from other tubes (56, 60, 64, 66) of the device, which is formed in the distributor body (32B) and which comprises a first section (68A), which is designed to be connected to a reservoir (24) for a flush medical fluid, and a second section (68B) opening directly into the chamber (62), said flush tube (68) being fitted with a valve (70, 80) equipped with a plug (70) which is located between the first and second sections (68A, 68B) of the flush tube and

which can be moved manually between a position in which it at least partly closes the flush tube and a position in which the flush tube (68) is in free communication with the chamber (62),

wherein the distributor provides an automatic connection via the chamber between the pressurised tube (64) and either the injection tube (60) or the pressure measurement tube (66) through the action of the pressure of the active medical fluid and the resilient member (120), the active medical fluid circulating via the compartment (126) between the pressurised tube (64) and the pressure measurement tube (66) when they are in connection, and

wherein the distributor (32) connects the flush tube (68) with the pressurised tube (64) and with the pressure measurement tube (66) via the chamber (62), the flush medical fluid circulating via the compartment (126) between the flush tube (68) and the pressure measurement tube (66) when they are in connection.

EVIDENCE APPENDIX:

NONE

RELATED PROCEEDINGS APPENDIX

NONE